# **OCS Analysis Studio 2.0:** Cutting-Edge Tools for Detecting Safety Signals and Crafting Review-Ready Tables and Figures

## Abstract

OCS Analysis Studio offers a set of fit-for-use, exploratory and flexible analysis tools for the clinical review process. These tools include the creation of tables and figures for application review, as well as data visualizations. Among the most used tools are Safety Explorer, Custom Table Builder, and Hepatic Explorer. These tools feature an intuitive and consistent user interfaces, empowering users to quickly create customized tabular and graphical analyses that conform to OND standard review guidance. Through a connection to the OCS Data Central service, users can utilize the Analysis Studio suite without the need for file uploads, by querying the specific application and studies to explore. Real-time interactivity allows users to rapidly interrogate signals of interest. These tools also allow for collaborative work, providing auditability and replicability through URL sharing and bookmarking. These tools have the capacity to export data outputs into Microsoft formats (xlsx and docx), allowing for easy integration into review documents. Analysis Studio tools are deployed in a cloud environment for enhanced speed, reliability, and diagnostics. Since July 2023, the site has over 2,000 analysis sessions performed by more than 500 unique users, supporting numerous clinical reviews and analyses.

## Introduction

[2018] Launched OCS Analysis Studio [2021] Migrated OCS Analysis Studio to FDA RAPID Cloud [2024] Releasing OCS Analysis Studio 2.0 in CDERone

#### Key Benefits of Analysis Studio 2.0

- URL Bookmarking easily reproduce and share analyses
- Direct connection to OCS *Data Central* service for data upload
- Architecture redesign for enterprise performance and scaling
- New potential for standard analysis automation
- Enhanced user metrics
- 8 tools in total: Safety Explorer, Custom Table Builder, Kidney Function, Hepatic Explorer, Shift Table, Listing Table, Custom MedDRA Query (CMQ) Builder, Scatterplot Grid

## Materials and methods



The OCS Analysis Studio 2.0 tools are built upon an architecture designed for stability and reproducibility. The new architecture leverages Microsoft .NET for the user interface and couples to a statistical computing engine built in R. The tool suite is containerized with Docker and has been hosted on Kubernetes-based servers on OCS platforms.



## **Results and discussion**

#### Samples of OCS Analysis Studio 2.0 Tool Outputs

#### SHIFT TABLE

The Shift Table Tool provides insight into the progression of study subjects' lab readings over time. Summary visualizations include a scatterplot figure and shift table organized by treatment group.

		Maximum BILI (	/ISIT = 'VISIT 5')		
Grouping Variable	Maximum BILI (LBBLFL = 'Y')	Group 1	Group 2	Group 3	Group 4
Placebo (N = 184)	Group 1	176 (95.7%)	1 (0.5%)	0 (0%)	0 (0%)
	Group 2	7 (3.8%)	0 (0%)	0 (0%)	0 (0%)
	Group 3	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Group 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Treatment 1 (N = 202)	Group 1	195 (96.5%)	1 (0.5%)	0 (0%)	0 (0%)
	Group 2	6 (3%)	0 (0%)	0 (0%)	0 (0%)
	Group 3	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Group 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Treatment 2 (N = 197)	Group 1	185 (93.9%)	1 (0.5%)	0 (0%)	0 (0%)
	Group 2	8 (4.1%)	0 (0%)	1 (0.5%)	0 (0%)
	Group 3	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
	Group 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)



### HEPATIC EXPLORER

This tool produces the industry-standard Drug-Induced Liver Injury (DILI) plot, with interactive subject-level selections allowing users to identify elevated on-treatment liver tests and assess candidates for hepatotoxicity.

Subject Narrative

Subject 201001157, a 50-year-old white male, was enrolled in

STUDY-2, a phase 3, randomized, double-blind, multicenter

study to evaluate the safety and efficacy of Treatment 1 and eatment 2 versus Placebo in the treatment of INDICATION or

INDICATION on 28 APR 2017. Vital signs at the screening visit

)8/62 mmHg. He had a known significant past medical history

drug use disorder (marijuana and amphetamine), tobacco

e, and Hepatitis C. The subject received the first dose of

adverse event of Worsening transaminases elevation

eatment 2 at 10:47 AM on 29 APR 2017 and the last dose a 2:21 PM on 01 MAY 2017. He received 5 doses of study drue

n 28 APR 2017 revealed heart rate 90 bpm, temperature 36.8ŰC. respiration 18 per minute, and blood pressure o

28 APR 2017. The subject was initially diagnosed with



#### SAFETY EXPLORER

Creates four standard summary tables of Treatment-Emergent Adverse Events (TEAEs):

- Summary of TEAEs
- Summary of Serious TEAEs
- Summary of TEAEs by Severity-Toxicity
- Summary of TEAEs Leading to Discontinuation

Provides users access to Risk Estimators and Forest Plots. columnlevel sorting, organization of tables by Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class and/or Preferred Term, optional display of tables based on user-uploaded Custom MedDRA Query (CMQ) Files, and filtering table by AE incidence percentage.



	Filter by Percentage -				
Summary of Serious TEAEs					
	Placebo	Treatment 1	Treatment 2		
System Organ Class	N = 290	N = 299	N = 294		
Preferred Term	🗘 n (%)	🗘 n (%)	‡ n (%)		
Any SAE	13 (4.5)	6 (2.0)	14 (4.8)		
Infections and infestations	8 (2.8)	4 (1.3)	10 (3.4)		
Abscess limb	0 (0.0)	1 (0.3)	2 (0.7)		
Bursitis infective	0 (0.0)	0 (0.0)	1 (0.3)		
Cellulitis	1 (0.3)	3 (1.0)	1 (0.3)		
Influenza	0 (0.0)	0 (0.0)	1 (0.3)		
Osteomyelitis	0 (0.0)	0 (0.0)	1 (0.3)		
Pneumonia	1 (0.3)	0 (0.0)	1 (0.3)		
Sepsis	1 (0.3)	0 (0.0)	1 (0.3)		
Skin bacterial infection	0 (0.0)	0 (0.0)	1 (0.3)		
Staphylococcal sepsis	0 (0.0)	0 (0.0)	1 (0.3)		
Respiratory, thoracic and mediastinal disorders		0 (0.0)	3 (1.0)		
Pleurisy	0 (0.0)	0 (0.0)	1 (0.3)		
Pulmonary embolism	0 (0.0)	0 (0.0)	1 (0.3)		
Sleep apnoea syndrome	0 (0.0)	0 (0.0)	1 (0.3)		
Injury, poisoning and procedural complications	1 (0.3)	1 (0.3)	1 (0.3)		
Limb injury	0 (0.0)	0 (0.0)	1 (0.3)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0.0)	0 (0.0)	1 (0.3)		
Rectal adenocarcinoma	0 (0.0)	0 (0.0)	1 (0.3)		

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<sup>1</sup>Food and Drug Administration (OCS/OTS/CDER) <sup>2</sup>IBM Corporation

#### **OCS Analysis Studio 2.0 Home Page**

SisStudio Home Tools - Help -			
Available Tools			
CMQ Tool	Welcome to	AnalysisStudio	
Custom Table			
Hepatic Explorer	AnalysisStudio is a flexible and user-friendly application that provides reviewers with multiple tools to create tabular and graphical analyses, with many outputs ready to incorporate into clinical reviews.		
Kidney Function	Please click on the available analyses listed analyses and to get started!	I on the left of the screen to learn more about the	
isting Table			
Safety Explorer			
Scatterplot Grid			
Shift Table			
		AnalysisStudio Home Tools - Help -	
		Hepatic Explorer	
		Data Source	
necting with the dat	ta hub - OCS Data Central	NDA/PLA number	
rect connection to O	CS Data Central repository	NDA214489	
itomated retrieval of	all available Application	Study ID iss	

- and Study datasets
- Automatic upload of all required datasets
- Support for SDTM and ADaM data
- Support for RDS, XPT, SAS7BDAT formats

## Conclusion

OCS Analysis Studio contains a set of intuitive and powerful exploratory tools that can be leveraged to aid clinical review through a range of general and specialized analyses. The new Analysis Studio 2.0 tool suite will reside in the CDER One Analytics platform to provide CDER users with an enterprise-grade analysis experience. Users may access new features that enable rapid reproduction of analyses, enhancements to data ingestion, and greater overall stability. There are additional enhancement in pipeline for Analysis Studio future versions where it can perform analysis beyond clinical review (e.g pharmacology, nonclinical)

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Hepatic Explorer							
Data Source							
Data Central Loo	al Upload Demo Data						
NDA/BLA number							
NDA214489	•						
Study ID							
iss	•						
Demographics dataset							
eCTD sequence number	File name (Data standard)						
0001 (2022-09-29)	adsl (ADaM)						
Chosen file path:							
\dc\NDA214489_0001_m5_iss_	ADaM_DA\adsl.rds						
Laboratory dataset							
eCTD sequence number	File name (Data standard)						
0001 (2022-09-29)	adlb (ADaM)						
Chosen file path:							
\dc\NDA214489_0001_m5_iss_	ADaM_DA\adlb.rds						